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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/592,011	10/22/2007	Stuart Edward Bradley	NC-10007/US	7007
38724 7590 04/16/2010 OSI PHARMACEUTICALS, INC. 41 PINELAWN ROAD MELVILLE, NY 11747				
EXAMINER				
POWERS, FIONA				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
04/16/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/592,011

Applicant(s)

BRADLEY ET AL.

Examiner

Fiona T. Powers

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15 and 19-27 is/are pending in the application.
- 4a) Of the above claim(s) 24-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 15 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1, 15 and 19 to 27 are pending in the application.

Receipt is acknowledged of the amendment filed April 6, 2010, which has been entered in the file.

Response to Amendment

The finality of the previous office action is withdrawn in view of the new rejections that follow.

Election/Restrictions

Claims 24 to 27 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 16, 2009.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 15, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no antecedent basis in the specification as originally filed for R being alkylaryl or alkylhetaryl as is now claimed. The specification only supports R being C₁₋₃alkylaryl and C₁₋₃alkylhetaryl.

To overcome this rejection, the definition of R in claim 1 should be amended by replacing "alkylaryl" with "aryl" and replacing "alkylhetaryl" with "hetaryl".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 15 and 19 to 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because the proviso in claim 1 excludes certain R^3 when -Y-Z represents $-C(NH)-(CH_2)_mNR-$. However, -Y-Z- is cannot be $-C(NH)-(CH_2)_mNR-$.

In claim 21, the phrase "the group consisting of" should be inserted after "from" and an "and" should be inserted between the last two compounds listed for proper Markush format.

In claim 22, the phrase "the group consisting of" should be inserted after "from" and an "and" should be inserted between the last two compounds listed for proper Markush format.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 15, 19 and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Nakamura et al. (CA 2465382), cited.

The reference discloses the claimed pharmaceutical compositions comprising a compound of instant formula I and a pharmaceutically acceptable carrier where the compound corresponds to instant formula I where Z is a bond; and R³ is C₁-alkylaryl. Note, for example, Compound Nos. 5-15, 5-16, 5-17, 5-18 and 5-19 on pages 196 to 197; page 33, lines 22 to 31; and Sections 12 to 20 on page 48, line 29 to page 50, line 1.

Response to Arguments

The rejection of the claims under 35 U.S.C. 112, second paragraph and 102(e) has been overcome by applicants amendment and/or argument.

Applicants request rejoinder of withdrawn method claims 24 to 27. However, since the product claims are not allowable, the method claims 24-27 will not be rejoined at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fiona T. Powers whose telephone number is 571-272-0702. The examiner can normally be reached on Mon & Wed 6:15 am - 5:45 pm and Tues & Thurs 6:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be

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reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fiona T. Powers/
Primary Examiner, Art Unit
1626

ftp
April 13, 2010